DOD CPB-ECMO INITIATIVE – A SUSPENDED ANIMATION FRONT LINES CASUALTY MANAGEMENT SYSTEM

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ABSTRACT

Cardiopulmonary bypass (CPB), the shunting of blood around the heart and lungs, is a well-established technique that permits difficult surgical procedures on the heart and its adjacent main blood vessels. Extracorporeal membrane oxygenation (ECMO) uses similar equipment, with the primary goal of temporary pulmonary support by increasing the oxygen content and decreasing the carbon dioxide content of the blood, without the intent of performing open chest surgery. It, too, is a well-developed clinical modality, often used in patients with acute respiratory failure. This project is developing a system of disposable, low cost CPB/ECMO components to treat front lines emergency trauma casualties. By cooling the patient to a low temperature of about 10°C and inducing a state of "suspended animation", a severe trauma victim could be preserved and transported to a medical unit capable of performing the required surgical treatment. The system prototype has completed major milestones including heat transfer requirements, CPB/ECMO commercial components selection, low cost disposable CPB pump, command/control console, and driver design fabrication, and extensive *in-vitro* testing. It is currently undergoing *in-vivo* testing in two animal models.

1. INTRODUCTION

The system has the following advantages: a) the equipment is economical - after patient transportation, the entire set can be discarded, rather than requiring components that must be refurbished and returned. The economy also allows CPB/ECMO capacity to be stockpiled, permitting a rapid expansion of services, should hostilities or a natural disaster require a sudden, temporary, large need for CPB surgery or pulmonary support, b) the device is very compact, and practical for transportation, c) the capability exists, given an adequate cooling water supply, to cool a large patient on a hot day to 10-15°C in 30 minutes, d) the system will automatically regulate flow to a set value, without frequent operator attention, over the entire range of possible circulating fluid compositions and temperatures.

2. SYSTEM DEVELOPMENT

2.1 Cannulae and Oxygenator Testing and Selection

Commercial oxygenators, as well as arterial and venous cannulae were evaluated to meet acceptance criteria based on lowest pressure drops and highest flows. The oxygenator, arterial and venous cannulae test setups consisted of a reservoir, 3/8" tubing connecting the reservoir with the cannula test chamber (1" diameter) and the pump. Care was taken to keep the distance between cannula outlet and pressure tap as short as possible. Flow was measured with an ultrasonic laboratory flow meter and probe (Transonic Inc., Ithaca NY). The pressure transducers (Abbott Laboratories, Morgan Hill CA) were calibrated before every test series to insure proper pressure reading. Data was acquired using a LabView (National Instruments, Austin TX) based data acquisition system.

2.2 Pump Design

The design of the rotary pump for this system was driven by the desire to meet performance requirements in an economical, disposable, small and efficient device. Efficiency is a much higher priority than would be usual in a traditional CPB pump, because of the requirements to power the pump with a low cost disposable motor, using a disposable battery pack, for patient transport. The design point for the pump was a blood flow of 5L/min at 350mmHg.

2.3 Control Console

The Electronic Control Unit (ECU) was intended for temporary use in a patient resuscitation, transportation, or maintenance mode, until definitive care could be rendered. The ECU is responsible for managing the system by providing an interface with the operator, displaying relevant data, accepting inputs from

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an incorporated keypad, and driving the blood pump motor. It also connects to the battery. The ECU was packaged in such a way as to allow simple and rapid deployment in an emergency. Its small footprint makes it readily transportable with the patient, to the point of definitive care, and economical enough to dispose, rather than refurbish and re-inventory.

2.4 Bench Testing

With successful completion of the controller and pump drive system, the complete system was performance and endurance tested in circulatory mock loops using different glycerin-water solutions. The final pump prototype was hemolysis tested using bovine blood and compared to a BioMedicus BP80 (Medtronic, Inc. MN) reference pump, an accepted high performance CPB pump. Hemolysis results were comparable to those of the BP80.

2.5 *In-Vivo* Testing

In-vivo testing of the system is underway in two distinct animal models: 1) CPB/ECMO in calves, and 2) Hypothermia and suspended animation in pigs.

3. RESULTS

Extensive bench testing results indicate that the system meets its performance design criteria, while retaining its low cost and portability. On going, *in-vivo* 6-hour CPB studies in calves show that the system is reliable, robust, and easy to operate.

4. CONCLUSIONS

A portable, low cost, ultimately disposable CPB/ECMO system for treating front lines emergency trauma casualties was successfully designed, developed, manufactured, and tested.

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